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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,185	01/24/2001	Francis Kalush	CL000280	1938

25748 7590 12/03/2002

CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/768,185

Applicant(s)

KALUSH ET AL.

Examin r

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-36 is/are pending in the application.
- 4a) Of the above claim(s) 22-25, 28-31 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-27, 32 is/are rejected.
- 7) ☒ Claim(s) 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of the nucleic acid sequence with a "T" at position 89837 of SEQ ID NO: 1 in Paper No. 13, 9/26/2002 is acknowledged. The traversal is on the ground(s) that the claims are drawn to nucleic acids having single polymorphisms at four different positions in SEQ ID NO: 1 which encode identical proteins. However, as set forth in the Restriction Requirement of Paper No. 9, 3/15/2002, the nucleic acids are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent utility, that is distinct for each invention which cannot be exchanged. Additionally, each Sequence requires a separate search, thus imposing a burden on the Examiner. .

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 18-21, 26-27, 32 are objected to because of the following informalities: The claims contain limitations drawn to non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-27, 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claims are drawn to a nucleic acid capable of hybridizing to a sequence set forth in SEQ ID NO: 1 having a T at position 89837 but not to a sequence set forth in SEQ ID NO: 1 having a G at position 89837. Applicant has provided a method of identifying the nucleic acid. In the specification (page 35, lines third paragraph to page 36, second paragraph).

Considering all disclosed distinguishing identifying characteristics such as:

A: Partial structure - No structure has been provided for the claimed nucleic acid capable of hybridizing to a sequence set forth in SEQ ID NO: 1 having a T at position 89837 but not to a sequence set forth in SEQ ID NO: 1 having a G at position 89837.

B: Physical and/or chemical properties - Physical or chemical properties are provided for the claimed nucleic acid.

C: Functional characteristics - The claimed nucleic acid must "be capable of hybridizing to a sequence set forth in SEQ ID NO: 1 having a T at position 89837 but not to a sequence set forth in SEQ ID NO: 1 having a G at position 89837".

D: Known or disclosed correlation between structure and function - No structural/functional relationship is disclosed for the claimed nucleic acid.

E: Method of making - No method of making is disclosed, only methods of identification.

F: Combinations of A-E - No combination of the other factors will adequately describe the claimed antagonist.

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Thus, in weighing all the factors in view of the level of skill and the knowledge in the art and in light of and consistent with the written description, one of skill in the art would recognize from the disclosure that Applicant was not in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-27, 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-27, 32 recites the term "high stringency conditions", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "stringent".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 26-27, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene (1991).

The Stratagene catalogue teaches the use of random 9-mers capable of hybridizing to all gene sequences. The random primers meet the limitations of claims 26-27 and 32 in that said primers are isolated DNA capable of hybridizing to a sequence set forth in SEQ ID NO: 1 having a T at position 89837 but not to a sequence set forth in SEQ ID NO: 1 having a G at position 89837 under the conditions provided in the claim.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
November 25, 2002